Section 502 (a), in that certain statements in the leaflet entitled "New Horizons" accompanying the device were false and misleading. The statements represented and suggested that use of the device was effective in improving the sexual capacities of older men by enlarging and reinforcing the sexual organ. The device was not effective for such purpose, and it would not fulfill the promises of benefit made for it.

The libel alleged also that if the leaflet entitled "New Horizons" was not part of the labeling of the device, then the device was misbranded when introduced into and while in interstate commerce within the meaning of Section 502 (f) (1), in that its labeling failed to state the purposes and conditions for which the device was intended, namely, to improve the sexual capacities of older men by enlarging and reinforcing the sexual organ.

DISPOSITION: June 13, 1952. Default decree of condemnation. The court ordered that the product be delivered to the Food and Drug Administration.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

4031. Adulteration and misbranding of Vio-Ferronate tablets. U. S. v. Rowell Laboratories, Inc. Plea of nolo contendere. Fine, $350. (F. D. C. No. 34351. Sample No. 48581–L.)

INFORMATION FILED: March 19, 1953, District of Minnesota, against Rowell Laboratories, Inc., Baudette, Minn.

ALLEGED SHIPMENT: On or about February 7, 1952, from the State of Minnesota into the State of North Dakota.

LABEL, IN PART: (Bottle) "Coated Tablets Vio-Ferronate Ferrous Gluconate with Liver and Vitamin B–12 * * * Rowell Laboratories Division of Burbot Liver Products Co. Baudette, Minnesota."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess since each tablet of the article purported and was represented to contain 3 milligrams of thiamine hydrochloride, 1 milligram of pyridoxine, and 30 milligrams of vitamin C, whereas each tablet contained less than 3 milligrams of thiamine hydrochloride, less than 1 milligram of pyridoxine, and less than 30 milligrams of vitamin C.

Misbranding, Section 502 (a), the label statements displayed upon the bottles were false and misleading in that the statements represented and suggested that each tablet of the article contained 3 milligrams of thiamine hydrochloride, 1 milligram of pyridoxine, and 30 milligrams of vitamin C (ascorbic acid), whereas each tablet contained less than 3 milligrams of thiamine hydrochloride, less than 1 milligram of pyridoxine, and less than 30 milligrams of vitamin C (ascorbic acid).

DISPOSITION: May 20, 1953. The defendant having entered a plea of nolo contendere, the court fined it $350.

4032. Adulteration and misbranding of gum karaya. U. S. v. 75 Drums * * *. (F. D. C. No. 33513. Sample No. 54058–L.)

LIBEL FILED: September 3, 1952, Northern District of Illinois.

ALLEGED SHIPMENT: On or about July 28, 1952, by Dodwell & Co., Ltd., from Newark, N. J.

PRODUCT: 75 300-pound drums of *gum karaya* at Franklin Park, Ill.

NATURE OF CHARGE: Adulteration, Section 501 (b), the product was represented to be "Gum Karaya," a drug, the name of which is recognized in the National Formulary, an official compendium, and its quality and purity fell below the standard set forth in such compendium since it contained more than 3 percent of bark and foreign and organic material and in a solution of the material (1 to 100), Millon's Reagent produced a yellow precipitate instead of a white precipitate as specified in the standard.

Misbranding, Section 502 (a), the label statement "Gum Karaya N. F." was false and misleading as applied to a product which failed to comply with the specifications in the National Formulary for gum karaya.

DISPOSITION: September 25, 1952. The shipper, claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be released under bond to be brought into compliance with the law, under the supervision of the Food and Drug Administration.

On July 23, 1953, an amended decree was entered which provided for the relabeling of the product to indicate that it was not National Formulary gum karaya and to indicate the manner in which it differed from the National Formulary product.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

4033. Misbranding of Kordolin tablets. U. S. v. 1,960 Bottles, etc. (F. D. C. No. 33242. Sample No. 23486–L.)

LIBEL FILED: May 7, 1952, District of New Jersey.

ALLEGED SHIPMENT: On or about April 3, 7, and 8, 1952, by the Kordol Corp., of America, from New York, N. Y.

PRODUCT: 1,960 100-tablet bottles and 864 50-tablet bottles of *Kordolin tablets* at Jersey City, N. J.

LABEL, IN PART: (Bottle) "Kordolin Tablets * * * Active Ingredients per tablet * Acket Acetphenetidin 2 gr. Calcium Succinate Caffeine Vitamin B_1 1 m. * Acket is Kordol Corporation of America's Brand Name of Salicylamide."

NATURE OF CHARGE: Misbranding, Section 502 (a), the labeling of the article, namely, the bottle label and the retail package carton, contained prominently displayed statements arranged to represent and suggest that the article was an adequate and effective treatment for arthritis, rheumatism, sciatica, bursitis, and neuritis, which statements were misleading since the article was not an adequate and effective treatment for such conditions; and the statement on the bottle labels and retail package cartons, namely, "Active Ingredients * * * Calcium Succinate Caffeine Vitamin B_1," was misleading since calcium succinate, caffeine, and vitamin B_1 were not active ingredients of the article for the purpose for which it was offered.

Further misbranding, Section 502 (c), the information required by Section 502 (e) (2) to appear on the label, namely, the common or usual name of each active ingredient, was not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, and devices in the labeling) and in such terms as to render it likely to be read and understood

*See also Nos. 4021, 4026, 4027, 4029–4032.